UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

RICK L. COLYER, et al.,

Plaintiffs,

v.

ACELRX PHARMACEUTICALS, INC., et al.,

Defendants.

Case No. 14-CV-04416-LHK

ORDER GRANTING MOTION TO DISMISS WITH LEAVE TO AMEND

Dkt. No. 35, 36

Plaintiffs Rick Colyer and Harry Zweifel (collectively, "Plaintiffs") bring this action against AcelRx Pharmaceuticals, Inc., Richard A. King, Timothy E. Morris, James H. Welch, and Pamela P. Palmer (collectively, "Defendants"). Before the Court are Defendants' motion to dismiss ("Mot") Plaintiffs' amended class action complaint ("AC") and Defendants' request for judicial notice ("RJN") of exhibits in support of this motion. *See* ECF No. 28 ("AC"); ECF No. 35 ("Mot."); ECF No. 36 ("RJN"). Having considered the parties' submissions, the relevant law, and the record in this case, the Court hereby GRANTS Defendants' request for judicial notice and GRANTS Defendants' motion to dismiss with leave to amend.

I. BACKGROUND

A. Factual Background

Traditionally, hospital patients with moderate-to-severe acute pain have used intravenous

patient-controlled analgesia treatment ("IV PCA") to manage their pain. AC ¶ 7. Although widely practiced, there are a number of limitations with IV PCA. First, IV PCA leaves most patients immobile because "patients [must be] tethered to an IV infusion pump with a line in the arm." *Id.* ¶ 42. Second, the most commonly used analgesics for IV PCA—morphine and hydromorphone—have a relatively low therapeutic index, measured as the ratio of an effective dose of analgesic versus a lethal dose of analgesic. *Id.* ¶ 48. Patients who use an analgesic with a lower therapeutic index thus face a higher risk of overdose than patients who use an analgesic with a higher therapeutic index. Third, the IV catheters used for IV PCA "are associated with infection risks," as any "break in the skin carries a risk of infection." *Id.* Fourth, patients who use IV PCA often experience analgesic gaps, defined as "interruptions in analgesic delivery." *Id.* ¶ 43. During these gaps, patients are "unable to self-administer the drug at the onset of pain." Analgesic gaps significantly disrupt and encumber effective pain management. *Id.*

Defendant AcelRx Pharmaceuticals ("AcelRx") is a publicly-traded company headquartered in Redwood City, California. *Id.* ¶ 19. Defendants Pamela P. Palmer ("Palmer"), Richard A. King ("King"), James H. Welch ("Welch"), and Timothy E. Morris ("Morris") are or were high-level executives at AcelRx. *Id.* ¶¶ 20–23. Over the past few years, AcelRx has dedicated considerable time and energy into developing an alternative to IV PCA. AcelRx's device, known as Zalviso, "allows patients to self-administer sublingual sufentanil" tablets. *Id.* ¶ 47. Like IV PCA, Zalviso is a combination product that works through the use of an analgesic, sufentanil, and a device that delivers that analgesic to the patient.

Unlike IV PCA, however, Zalviso delivers sufentanil sublingually (i.e., under the tongue). *Id.* ¶ 48. "[S]ufentanil doses . . . are preloaded into a cartridge that is loaded into a device. Once the cartridge is loaded into the device, a priming capsule is discharged by the nurse, signaling that the device is ready for the patient's use, and also locking the cartridge within the device." *Id.* Patients use a pre-programmed, handheld control to adjust the amount of analgesic they need. The control employs an optical sensor to help moderate how much sufentanil patients can receive, and locks up "for a set period of time between doses." *Id.* ¶ 76. "The optical system is important

because . . . it is intended to prevent situations where a patient does not receive their dose (due to a device malfunction) and the nurse mistakenly thinks that the patient has received the dose (in which case, the patient would be without any pain medication while the device remains locked)." *Id.* An optical system error is thus functionally equivalent to an analgesic gap: in both situations, patients are unable to self-administer the analgesic that they have been prescribed.

According to AcelRx, Zalviso improves upon IV PCA in a number of ways. First, "[i]n animal studies, the therapeutic index for sufentanil was approximately . . . 300 times [higher] than morphine." *Id.* n.1. Second, unlike IV PCA, Zalviso provides a "non-invasive route of delivery." *Id.* ¶ 53. Patients thus have greater mobility and, more importantly, are not exposed to the risk of IV-related infection. *Id.* Finally, Zalviso's delivery system "eliminate[s] the risk of infusion pump programming errors"—the sort of analgesic gaps that afflicted patients using IV PCA. *Id.*

On September 30, 2013, AcelRx submitted to the FDA a new drug application ("NDA") for Zalviso. *Id.* ¶ 62. The NDA approval process is one of the final steps that a company must take before a drug or device may be sold to the public. Prior to submitting Zalviso's NDA, AcelRx had conducted seven Phase 1 studies, three Phase 2 studies, and three Phase 3 trials.[1] AcelRx reported that Phase 3 trials were successful in meeting Zalviso's targeted endpoints.

On December 2, 2013, the FDA announced that it had accepted Zalviso's NDA for review. *Id.* ¶ 5. On July 25, 2014, AcelRx received a Complete Response Letter ("CRL") from the FDA. *Id.* ¶ 11. According to AcelRx, in the CRL, the FDA "requested additional information on the Zalviso System to ensure proper use of the device, including the provision of bench data demonstrating a reduction in the incidence of optical system errors, changes to the Instructions for Use for the device, and additional data to support the shelf life of the product." *Id.* Plaintiffs

[1] The FDA requires companies to conduct three phases of studies prior to submission of an NDA. Phase 1 studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." 21 C.F.R. § 312.21(a)(1). Phase 2 studies are "conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study." 21 C.F.R. § 312.21(b). Finally, Phase 3 clinical trials "are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug." 21 C.F.R. § 312.21(c).

allege that, based on this news, AcelRx shares immediately declined by nearly 41%.

B. Procedural History

On October 1, 2014, Plaintiffs filed their first complaint in this putative class action. ECF No. 1. Plaintiffs filed an amended complaint on April 17, 2015. In the amended complaint, Plaintiffs seek to represent a class comprised of all persons "who purchased or otherwise acquired AcelRx's common stock and/or call options, or sold/wrote AcelRx's put options between September 30, 2013 [the day that AcelRx submitted the NDA for Zalviso] and July 25, 2014 [the day that AcelRx received the CRL for Zalviso]." AC ¶ 1.

Plaintiffs allege that Defendants made "materially false and/or misleading" statements in various press releases and SEC filings during this class period in violation of § 10(b) of the Exchange Act and Rule 10b-5. *See, e.g., id.* ¶¶ 13, 102; *see also* 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5. Specifically, Plaintiffs allege that Defendants failed to disclose "a substantial and existing defect with the Phase 3 Device that caused the device to malfunction"—the optical system errors. AC ¶ 102. Further, Plaintiffs allege that these optical system errors occurred at a sufficiently high rate such "that the issue would certainly [have] draw[n] attention from the FDA" and would have "very likely . . . require[d] the company to conduct" additional trials for Zalviso. *Id.* Plaintiffs note that AcelRx had also designed a modified device in an attempt to address these errors, but that AcelRx had failed to disclose this fact in AcelRx's press releases or public filings during the class period. Finally, Plaintiffs allege that the individual Defendants (Palmer, King, Morris, and Welch) are controlling persons of AcelRx and are therefore liable under § 20(a) of the Exchange Act.

On June 1, 2015, Defendants filed the instant motion to dismiss. ECF No. 35. Plaintiffs filed an opposition to Defendants' motion on July 30, 2015, and Defendants filed a reply on September 14, 2015. ECF No. 43 ("Opp'n"); ECF No. 47 ("Reply"). On June 1, 2015, Defendants also filed a request for judicial notice of various exhibits filed in support of Defendants' motion to dismiss. ECF No. 36. Plaintiffs filed an opposition to Defendants' request on July 30, 2015, and Defendants filed a reply on September 14, 2015. ECF Nos. 42 & 50. The

Court first addresses Defendants' request for judicial notice then addresses Defendants' motion to dismiss.

II. JUDICIAL NOTICE

Defendants request judicial notice of fifteen exhibits filed in support of Defendants' motion to dismiss. The Court reviews these exhibits in turn.

Exhibits 1 through 5 and 10 through 12 are public SEC filings. Such filings are generally subject to judicial notice. *Metzler Inv. GMBH v. Corinthian Coll., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008) ("SEC filings [are] subject to judicial notice."). Plaintiffs nonetheless object to the inferences that Defendants purportedly seek to draw from Exhibit 12 because, Plaintiffs argue, such documents may not be used "to prove the truth of their contents." ECF No. 42 at 4 (internal quotation marks omitted).[2] This argument simply recasts the well-accepted legal standard governing documents subject to judicial notice—that is, that the Court "may take judicial notice of publications introduced to indicate what was in the public realm at the time," but that the Court may not take judicial notice as to "whether the contents of those articles were in fact true." *Von Saher v. Norton Simon Museum of Art*, 592 F.3d 954, 960 (9th Cir. 2009) (internal quotation marks omitted). The Court will bear this standard in mind with respect to Exhibit 12, as the Court must bear in mind with respect to all of Defendants' exhibits. Plaintiffs' objection, however, does not warrant rejection of Defendants' request for judicial notice. Accordingly, the Court GRANTS Defendants' request for judicial notice of Exhibits 1 through 5 and 10 through 12.

Exhibit 9 is an FDA document providing guidance on the approval process for combination products. Exhibits 13 through 15 are patent filings and other related materials filed with the U.S. Patent and Trademark Office. All of these documents are in the public record, and all are subject to judicial notice. *See Oroamerica Inc. v. D & W Jewelry Co., Inc.*, 10 F. App'x 516, 517 n.4 (9th Cir. 2001) (granting judicial notice to public documents associated with design patent). Plaintiffs have not specifically opposed Defendants' request that the Court take judicial

[2] Plaintiffs did not raise specific objections with regard to Exhibits 1 through 5 or Exhibits 10 and 11.

notice of these three exhibits. Accordingly, the Court GRANTS Defendants' request for judicial notice of Exhibit 9 and Exhibits 13 through 15.

Exhibit 7 is a press release that provides background on AcelRx's patent portfolio. "Courts in the Ninth Circuit routinely take judicial notice of press releases." *In re Am. Apparel, Inc. S'holder Litig.*, 855 F. Supp. 2d 1043, 1062 (C.D. Cal. 2012). Plaintiffs have not specifically opposed Defendants' request that the Court take judicial notice of Exhibit 7. Accordingly, the Court GRANTS Defendants' request for judicial notice of Exhibit 7.

Finally, Exhibits 6 and 8 are conference call transcripts. In Exhibit 6, a transcript from a conference call that occurred on July 28, 2014, Defendants discuss the implications of the FDA's decision to withhold approval for Zalviso. ECF No. 37 at 7. In Exhibit 8, a transcript from a conference call that occurred on March 9, 2015, Defendants discuss AcelRx's fourth quarter financial earnings. *Id.* As Plaintiffs concede, the amended complaint refers to both calls on multiple occasions. *See, e.g.*, AC ¶¶ 80, 83, 116, 129. In fact, the amended complaint quotes extensively from the transcripts of both calls. Other district courts have found conference call transcripts subject to judicial notice, particularly where portions of these transcripts are quoted at length in the complaint. *See In re Am. Apparel*, 855 F. Supp. 2d at 1061; *In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 864 (N.D. Cal. 2004). The Court finds it appropriate to take judicial notice of the transcripts at issue. Plaintiffs cannot selectively quote from one part of a publicly-available transcript and then object to Defendants' decision to provide the Court with the complete transcript. Accordingly, the Court GRANTS Defendants' request for judicial notice of Exhibits 6 and 8.

In sum, the Court finds that all of Defendants' exhibits are subject to judicial notice. Defendants' request for judicial notice is therefore GRANTED in its entirety.

III. LEGAL STANDARDS

A. Motion to Dismiss

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss an action for failure to state a claim upon which relief may be granted. Because Plaintiffs have

brought their claims as a federal securities fraud action, Plaintiffs are not subject to the notice pleading standards under Federal Rule of Civil Procedure 8(a)(2), which require litigants to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Instead, Plaintiffs must "meet the higher, [more] exacting pleading standards of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (PSLRA)." *Or. Pub. Emp. Ret. Fund v. Apollo Group Inc.*, 774 F.3d 598, 603–04 (9th Cir. 2014).

Under Federal Rule of Civil Procedure 9(b), "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Plaintiffs must include "an account of the time, place, and specific content of the false representations" at issue. *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (internal quotation marks omitted). Rule 9(b)'s particularity requirement "applies to all elements of a securities fraud action." 774 F.3d at 605. "PSLRA imposes additional specific pleading requirements, including requiring plaintiffs to state with particularity both the facts constituting the alleged violation and the facts evidencing scienter." *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012). In order to properly allege falsity, "a securities fraud complaint must . . . specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." *Id.* (internal quotation marks and alteration omitted). In addition, in order to "adequately plead scienter under the PSLRA, the complaint must state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* (internal quotation marks omitted).

For purposes of ruling on a Rule 12(b)(6) motion, the Court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, the Court is not required to "'assume the truth of legal conclusions merely because they are cast in the form of factual allegations.'" *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011) (quoting *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981)). Mere "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss." *Adams v. Johnson*, 355 F.3d 1179, 1183 (9th Cir. 2004). Furthermore, "'a plaintiff may plead

[him]self out of court'" if he "plead[s] facts which establish that he cannot prevail on his . . . claim." *Weisbuch v. Cnty. of L.A.*, 119 F.3d 778, 783 n.1 (9th Cir. 1997) (quoting *Warzon v. Drew*, 60 F.3d 1234, 1239 (7th Cir. 1995)).

B. Leave to Amend

Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend "shall be freely granted when justice so requires," bearing in mind "the underlying purpose of Rule 15 to facilitate decision on the merits, rather than on the pleadings or technicalities." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation marks and alterations omitted). Generally, leave to amend shall be denied only if allowing amendment would unduly prejudice the opposing party, cause undue delay, or be futile, or if the moving party has acted in bad faith. *Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 532 (9th Cir. 2008).

IV. DISCUSSION

A. Violation of § 10(b) of the Exchange Act and Rule 10b-5

"To plead a claim under section 10(b) and Rule 10b–5, [] Plaintiffs must allege: (1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *Or. Pub. Emp. Ret. Fund*, 774 F.3d at 603. Defendants argue that Plaintiffs have failed to sufficiently allege that Defendants committed a material misrepresentation or omission and that Plaintiffs have failed to show that Defendants' alleged actions support a strong inference of scienter. The Court analyzes these contentions in turn.

1. Material Misrepresentation or Omission

The amended complaint is rife with purported examples of Defendants' materially false and/or misleading statements. These statements can be broadly organized into four categories: (a) statements that relate to the clinical history of Zalviso prior to submission of the NDA, (b) statements that trumpet Zalviso's alleged superiority to IV PCA, (c) statements that reveal insufficient disclosure of the risks of Zalviso, and (d) misleading forward-looking statements. As the Court will show, no statement in any of these categories rises to the level of a material

misrepresentation or omission necessary to state a claim under § 10(b) or Rule 10(b)-5.

a. Clinical History of Zalviso Prior to NDA

First, Plaintiffs allege that AcelRx made statements "regarding their NDA submission and [regarding] the status of the NDA" that were "materially false and/or misleading." Opp'n at 5–6. Plaintiffs, for instance, emphasize the following statement made by AcelRx in a September 30, 2013 press release:

> The NDA submission is based primarily on data from a Phase 3 registration program that included two double-blind randomized placebo-controlled clinical trials, one conducted in patients following major abdominal surgery, the other in patients following major joint replacement surgery. Additionally, a Phase 3 open-label active-comparator trial was conducted in patients following either major abdominal or orthopedic surgery, comparing Zalviso to the current standard of care, intravenous patient-controlled analgesia (IV PCA) with morphine. Zalviso successfully achieved the primary efficacy endpoints for each of these studies. Treatment-emergent adverse events were typical of opioid usage post-operatively, were generally mild-to-moderate in nature, and were similar in both active- and placebo-treatment groups for the majority of adverse events.

AC ¶ 100. The Court fails to see how this statement, or statements to this effect, *see, e.g.*, *id.* ¶¶ 103 & 106, are "materially false and/or misleading." This statement does not shed light upon the likelihood of FDA approval for Zalviso. In fact, this statement does not even express an opinion as to the results of Zalviso's Phase 3 trials. Rather, this statement merely summarizes the process that AcelRx undertook prior to submitting Zalviso for FDA approval. As Plaintiffs acknowledge, AcelRx did in fact conduct three Phase 3 trials and AcelRx did in fact achieve the primary endpoints in each of these trials. *Id.* ¶ 66.

Thus, these clinical history statements were not false. In fact, they were (and are) quite literally true. These statements were also not misleading. As the Ninth Circuit has held, § 10(b) and Rule 10b-5 "prohibit *only* misleading and untrue statements, not statements that are incomplete." *Brody v. Transitional Hosp. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). An omission is misleading if it "affirmatively create[s] an impression of a state of affairs that differs in a material way from the one that actually exists." *Id.* The clinical history statements do not

create such an impression. These statements do not suggest or imply that AcelRx believed that the FDA would give approval for Zalviso. Instead, these statements provide an accurate snapshot of the work that AcelRx undertook prior to submission of Zalviso's NDA. Such statements are not misleading for purposes of § 10(b) and Rule 10b-5.

b. Zalviso's Superiority to IV PCA

Next, Plaintiffs contend that "Defendants made materially false and/or misleading positive statements trumpeting Zalviso's superiority to the IV PCA." Opp'n at 6. According to Plaintiffs, Defendants touted the effectiveness of Zalviso but withheld from the public the fact that Zalviso was affected by optical system errors. In the amended complaint, Plaintiffs emphasize the following statements, made by AcelRx in a number of public SEC filings during the class period:

> Zalviso is designed to address the limitation of IV PCA by offering . . . [a] non-invasive route of delivery[.] The sublingual route of delivery used by Zalviso provides rapid onset of analgesia, therefore eliminating the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections in IV PCA treated patients. In addition, because patients are not tethered to IV tubing and a pump for pain relief, Zalviso allows for ease of patient mobility.

AC ¶ 104. Plaintiffs argue that these statements were misleading because they created an impression that Zalviso eliminated the risk of *all* analgesic gaps and *all* complications, not just those analgesic gaps and complications associated with IV PCA.

Plaintiffs' analysis is not well taken. Plaintiffs do not contest the truth of the following statements: Zalviso eliminates the risk of IV-related analgesic gaps, Zalviso eliminates the risk of certain other IV-specific complications, and Zalviso provides patients with greater ease of mobility. Instead, Plaintiffs claim that Defendants should have also disclosed Zalviso's optical system error rate. Plaintiffs contend that, without including this information, Defendants' statements implied that Zalviso would eliminate analgesic gaps altogether.

This is not a reasonable interpretation of Defendants' statements. Defendants' statements make clear that Zalviso would eliminate *IV-related* analgesic gaps and other *IV-related* complications *because of* Zalviso's "sublingual route of delivery"—that is, because Zalviso did not require patients to use an IV catheter to receive pain medication. AC ¶ 104. Such statements

do not state or imply that Zalviso would eliminate the risk of *all* analgesic gaps or *all* complications. At most, Defendants' statements comparing Zalviso's efficacy to IV PCA are incomplete, as these statements do not disclose that Zalviso might come with its own set of risks. However, AcelRx never promised investors that Zalviso would be a perfect device, and a reasonable investor would not read Defendants' statements to imply such a conclusion.

In Plaintiffs' opposition to the instant motion, Plaintiffs cite a number of cases where courts have allegedly found that literally true statements can nonetheless be misleading. Opp'n at 6–7. These cases, however, do not support Plaintiffs' contentions. Both *Church of Scientology Flag Service Organization, Inc. v. City of Clearwater*, 2 F.3d 1514 (11th Cir. 1993), and *K & T Enterprises, Inc. v. Zurich Insurance Co.*, 97 F.3d 171, 180–81 (6th Cir. 1996), have nothing to do with securities fraud. The former case concerns the First Amendment implications of an ordinance regulating the solicitation of funds by charitable organizations. The latter case centers on an insurance dispute which required the interpretation of various fraud and misrepresentation provisions in Michigan state law. Neither case is helpful in determining whether Defendants here made a misleading statement for purposes of federal securities fraud liability.

The remaining cases relied upon by Plaintiffs are likewise inapposite. In *Brody v. Transitional Hospitals Corp.*, the Ninth Circuit rejected the plaintiffs' contention that certain statements made by the defendants were misleading. Although the Ninth Circuit acknowledged that some statements can be both "literally true" and "misleading," the Ninth Circuit also made clear that Rule 10b-5 liability does not attach to statements that are simply incomplete. 280 F.3d at 1006. In fact, "*[o]ften*, a statement will not mislead even if it is incomplete or does not include all relevant facts." *Id.* (emphasis added). "No matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not." *Id.; see also Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008) ("[T]he securities laws don't require firms to disclose all information."). The Ninth Circuit went on to explain that, "in order to survive a motion to dismiss under the heightened pleading standards of the [PSLRA], the plaintiffs' complaint must specify the reason or reasons why the statements

made . . . were misleading or untrue, not simply why the statements were incomplete." *Brody*, 280 F.3d at 1006. Plaintiffs in the instant case have failed to clear this hurdle. At most, Defendants' statements were incomplete, not misleading.

Finally, Plaintiffs cite *Operating Local 649 Annuity Trust Fund v. Smith Barney Fund Management LLC*, 595 F.3d 86 (2d Cir. 2010), where the Second Circuit determined that the defendants did make a materially misleading omission. Yet, in reaching this conclusion, the Second Circuit emphasized that the defendants had omitted information that the defendants were required to disclose under SEC disclosure rules. *Id.* at 92–95. Plaintiffs in the instant case have identified no such applicable rules which require disclosure of Zalviso's alleged shortcomings.

To summarize, Defendants were under no obligation to reveal Zalviso's alleged shortcomings in statements comparing Zalviso to IV PCA. Defendants did not make false or misleading statements when comparing Zalviso to IV PCA. Defendants' statements were in fact literally true and were, at most, incomplete. Under such circumstances, Plaintiffs have failed to state a claim upon which relief may be granted under § 10(b) and Rule 10b-5.

c. Insufficient Disclosure of Risk/Need for Additional Device Testing

Plaintiffs also contend that Defendants' risk disclosures contained materially false and/or misleading statements because these disclosures did not mention Zalviso's optical system error rate. Plaintiffs point specifically to the following language from AcelRx's risk disclosures:

> We have conducted multiple Design Validation, Software Verification and Validation, Reprocessing and Human Factors studies, which have informed the design of the Zalviso device and we plan to conduct additional Human Factors studies prior to submitting the planned NDA for Zalviso. However, we cannot predict if the Phase 3 device will be fully functional or ready for commercial use. If we need to modify the Phase 3 device, we may incur higher costs and experience delay in regulatory approval and commercialization of Zalviso. Furthermore, if the changes to the device are substantial, we may need to conduct further clinical trials in order to have the commercial device approved by the FDA.

AC ¶ 101. These risk disclosures do not mention that Defendants were designing a modified device to address Zalviso's optical system errors. According to Plaintiffs, Defendants' decision to

design such a device is evidence of Defendants' knowledge "that the optical system errors occurred at a substantially high enough rate [to] . . . at least draw careful scrutiny from the FDA." Opp'n at 8. These errors "created a substantial risk, undisclosed to investors, that the FDA, aware of the existence of a superior and safer device, would require [AcelRx] to conduct trials sufficient to generate data to demonstrate the safety and effectiveness of the Modified Phase 3 Device before the FDA would approve Zalviso." *Id.* (footnote omitted). Defendants' risk disclosure statements were therefore, under Plaintiffs' theory, misleading.

The Court is unconvinced by this argument. As a threshold matter, AcelRx's decision to improve upon the design of one of its products cannot, by itself, give rise to a federal securities fraud action. A company does not commit securities fraud when it decides to improve upon one of its products, and seeks patent protection for some of these improvements. More importantly, Plaintiffs have offered no response to Defendants' plausible explanation that AcelRx would first "seek approval of the clinically tested [Phase 3] design, launch that product[,] and then seek approval of any design changes thereafter." Mot. at 18; *see also* AC ¶ 83 (noting that Defendants viewed the optical system errors as "a commercial issue," and not as a regulatory issue) (internal quotation marks omitted). In fact, Plaintiffs' only response to Defendants' explanation is to state that this explanation "is no excuse for not telling investors of the inferiority of the device used in the Phase 3 trials." Opp'n at 10. Yet Plaintiffs have provided no legal support, and the Court has found none, as to why Defendants' actions were inexcusable or, more importantly, actionable under § 10(b) and Rule 10b-5.

In fact, governing precedent from the U.S. Supreme Court and the Ninth Circuit points toward the opposite conclusion. In *Matrixx Initiatives v. Siracusano*, 131 S. Ct. 1309, 1321 (2011), the U.S. Supreme Court stated that "§ 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information." Rather, "[d]isclosure is required only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *Id.* (internal quotation marks and alteration omitted). "Even with respect to information that a reasonable investor might consider material, companies can control

what they have to disclose under these provisions by controlling what they say to the market." *Id.* at 1322. In interpreting *Matrixx*, the Ninth Circuit has held that "as long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant." *In re Rigel*, 697 F.3d at 880 n.8. "The materiality of information is different from the issue of whether a statement is false or misleading." *Id.*

Together, *In re Rigel* and *Matrixx Initiatives* provide a clear answer to the alleged omissions at issue. Under these cases, Plaintiffs must show (1) that statements made by AcelRx were actually misleading, *and* (2) that disclosure of certain information would have made these statements not misleading. The Court finds, under step (1), that there was nothing misleading about AcelRx's risk disclosure statements.

These risk disclosure statements begin by summarizing the studies AcelRx undertook prior to submission of the NDA. *See* AC ¶ 101 ("We have conducted multiple Design Validation, Software Verification and Validation, Reprocessing and Human Factors studies, which have informed the design of the Zalviso device and we plan to conduct additional Human Factors studies prior to submitting the planned NDA for Zalviso."). This summary is akin to the clinical history statements that were previously described and analyzed. As with those clinical history statements, this summary is not actionable under § 10(b) and Rule 10b-5. The risk disclosure statements continue by noting that "we [AcelRx] cannot predict if the Phase 3 device will be fully functional or ready for commercial use." This sentence is not misleading. If anything, this sentence makes clear that Defendants were uncertain about Zalviso's prospects for FDA approval, and that Defendants could not provide any guarantees as to Zalviso's market horizon. Finally, the risk disclosure statements conclude: "If we need to modify the Phase 3 device, we may incur higher costs and experience delay in regulatory approval and commercialization of Zalviso. Furthermore, if the changes to the device are substantial, we may need to conduct further clinical trials in order to have the commercial device approved by the FDA." Again, these sentences are

not misleading. They are in fact an accurate description of the regulatory process. As outlined in 21 U.S.C. § 356a, if a company does decide to make changes to the manufacturing process of a particular drug, the company must notify the FDA. If the change "is not a major manufacturing change," the company need only comply with a set of requirements not nearly as onerous as those required for approval of a new drug. 21 U.S.C. § 356a(d). However, if the change is "a major manufacturing change," the company may need to submit a more detailed "supplemental application." 21 U.S.C. § 356a(c). The Court fails to see how sentences which accurately summarize this process can be misleading.

Setting aside the specific language in the risk disclosure statements for a moment, the gist of Plaintiffs' complaint is that Defendants knew about a risk that would jeopardize FDA approval for Zalviso and that Defendants did not publicly disclose this risk. Under *In re Rigel* and *Matrixx Initiatives*, however, knowledge alone is insufficient for § 10(b) and Rule 10b-5 liability. Again, "a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant." *In re Rigel*, 697 F.3d at 880 n.8. In addition, "[t]he materiality of information is different from the issue of whether a statement is false or misleading." *Id.* Thus, what matters is not whether the omitted information was significant, but whether, absent the omitted information, Defendants' statements were misleading. As the Court has made clear, Defendants' statements were not misleading.

Moreover, the Court also finds that Plaintiffs have failed to explain how Defendants' knowledge of Zalviso's optical system errors would necessarily translate into knowledge that Zalviso would face a significantly higher risk of rejection by the FDA. Plaintiffs cite *In re Connetics Corporation Securities Litigation*, 2008 WL 3842938 (N.D. Cal. Aug. 14, 2008), and *In re Merck & Co., Inc., Inc. Securities, Derivative, & ERISA Litigation*, 2011 WL 3444199 (D.N.J. Aug. 8, 2011), but these cases do not support Plaintiffs' position. First, both cases were decided prior to *Matrixx Initiatives* and prior to *In re Rigel*. Plaintiffs have not explained why the Court should rely upon *In re Connetics* and *In re Merck* in light of subsequent U.S. Supreme Court and

Ninth Circuit case law. In any event, the Court finds *In re Connetics* and *In re Merck* inapposite. As the district court in *In re Connetics* noted, the defendants "had actual knowledge of the results of [a] transgenic mouse study, and defendants also knew, as they themselves aver, that very few other drugs with similar test results had been approved by the FDA." 2008 WL 3842938, *7. In addition, in *In re Merck*, the defendants "deliberately deferred conducting a large-scale trial . . . which would compare Vioxx and a traditional NSAID, for fear that it would show a greater incidence of adverse . . . events in Vioxx users." 2011 WL 3444199, at *11. Thus, in both *In re Connetics* and *In re Merck*, the plaintiffs alleged that the companies knew about a drug's shortcomings, that these shortcomings had resulted in rejection of similar drugs, and that the companies actively withheld information about these shortcomings to investors.

There have been no such allegations made in the instant case. Indeed, unlike the defendants in *In re Connetics* and *In re Merck*, Plaintiffs here have not alleged that Defendants knew that "very few other drugs with similar test results had been approved by the FDA," or even that there were other drugs or devices to which Defendants could compare Zalviso. 2008 WL 3842938, at *7. When asked by a market analyst whether there had been "any guidance from the [FDA] or any prior precedence with other devices or products where [the FDA] have [sic] asked for [a] certain threshold on optical error rate," then-AcelRx CEO Richard King responded: "None that I'm aware of. This is a system that is incorporated into our technology which is specific to our technology. So I am unaware of any other request." AC ¶ 80; *see also* AC ¶ 84 ("[W]e haven't been given a specific target rate" for the optical system errors.). There is no indication that Defendants knew that Zalviso's optical system error rate would be cause for concern for the FDA.[3]

To summarize, Plaintiffs have failed to show that Defendants' actual risk disclosures were

[3] In Plaintiffs' opposition to the instant motion, Plaintiffs contend that "the FDA is likely to deem any error risking patient safety . . . statistically significant, particularly when [as with Zalviso] the error rate is in excess of 5%." Opp'n at 12 n.11. Plaintiffs, however, have not provided any support for this legal conclusion and, for purposes of a motion to dismiss, the Court is not required to "assume the truth of legal conclusions merely because they are cast in the form of factual allegations." *Fayer v. Vaughn*, 649 F.3d at 1064 (internal quotation marks omitted).

misleading as required under *In re Rigel* and under *Matrixx Initiatives.* The authority that Plaintiffs do rely upon predates both of these cases and, in any event, does not support Plaintiffs' claims. Accordingly, the Court finds that Plaintiffs have failed to state a claim under § 10(b) and Rule 10b-5 for the alleged omissions in Defendants' risk disclosures.

d. Forward-Looking Statements

Finally, Plaintiffs allege that Defendants made certain forward-looking statements about the outlook of Zalviso that were materially false and/or misleading. In particular, Plaintiffs point to statements such as the following, made in AcelRx's 10-K:

> [A]ssuming successful approval of our NDA . . . , we anticipate launching the commercial sale of Zalviso in the United States in the first quarter of 2015.

AC ¶ 110. According to Plaintiffs, these statements misled investors into believing that the FDA would approve Zalviso, despite the fact that Defendants knew Zalviso would not receive approval because of the device's optical system errors.

Plaintiffs' contentions are not well taken. Under PSLRA, a forward-looking statement is defined to include any "statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issue" and "any statement of the assumptions underlying or relating to any [such] statement." 15 U.S.C. § 78u-5(i)(1). PSLRA further provides that:

> [A] person . . . shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that—
>
> (A) the forward-looking statement is—
> (i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or
> (ii) immaterial; or
>
> (B) the plaintiff fails to prove that the forward-looking statement—
> (i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or
> (ii) if made by a business entity; was—
> (I) made by or with the approval of an executive officer of that entity; and
> (II) made or approved by such officer with actual knowledge by that officer that

the statement was false or misleading.

15 U.S.C. § 78u–5(c)(1) (footnote omitted). Together, these terms provide a safe harbor for forward-looking statements. In fact, according to the Ninth Circuit, these terms provide two safe harbors: one safe harbor for forward-looking statements identified as such and accompanied by meaningful cautionary statements, *see* 15 U.S.C. § 78u–5(c)(1)(A) ("Subsection A"), and another safe harbor for "unidentified forward-looking statements and forward-looking statements unaccompanied by meaningful cautionary language," *see* 15 U.S.C. § 78u–5(c)(1)(B) ("Subsection B"). *See In re Cutera Sec. Litig.*, 610 F.3d 1103, 1112–13 (9th Cir. 2010) (explaining how the safe harbors work together).

The statements recited above are clearly forward-looking statements as defined under Subsection A. These statements provide detail on the planned rollout of Zalviso. They thus fall within the purview of "statements of the plans and objectives of management for future operations." 15 U.S.C. § 78u-5(i)(1). In addition, these statements were identified as forward-looking statements by Defendants. The very first page of AcelRx's 10-K states, for instance, that "[t]his Annual Report . . . contains 'forward-looking statements' within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the 'safe harbor' created by that section." R. 37-4 ("2013 10-K") at 3. Further, the 10-K provides that investors "can identify forward-looking statements by the following words: 'may,' 'will,' 'could,' . . . '*anticipate*." *Id.* (emphasis added); *see* AC ¶ 110 ("[W]e anticipate launching the commercial sale of Zalviso in the United States in the first quarter of 2015."). The 10-K also lists several factors "that could cause actual results to differ materially from those in the forward-looking statement." *Id*. These factors include the "ability to obtain and maintain regulatory approval of Zalviso," "the success, cost and timing of . . . product development activities and clinical trials," and any "regulatory developments in the United States and foreign countries. 2013 10-K at 3. In sum, the statements at issue fall under the Subsection A safe harbor because they are forward-looking statements, were identified as such, and were accompanied by meaningful cautionary statements.

Plaintiffs' arguments to the contrary are unavailing. First, Plaintiffs argue that "Defendants cannot knowingly mislead the public, while shielding themselves from liability by adding some cautionary language." Opp'n at 10 n.8. This argument appears to relate to a different safe-harbor provision— Subsection B. That safe harbor provides that a person shall not be liable for forward-looking statements if "the plaintiff fails to prove that the forward-looking statement . . . was made with actual knowledge by that person that the statement was false or misleading." 15 U.S.C. § 78u–5(c)(1)(B). However, as the Court has held, the instant statements are not governed by Subsection B, which applies to unidentified forward-looking statements and forward-looking statements unaccompanied by meaningful cautionary language, but by Subsection A. To reiterate, the forward-looking statements at issue were identified by AcelRx as being forward-looking statements and were accompanied by meaningful cautionary language. As the Ninth Circuit has held, "if a forward-looking statement is identified as such and accompanied by meaningful cautionary statements, then the state of mind of the individual making the statement is irrelevant, and the statement is not actionable regardless of the plaintiff's showing of scienter." *In re Cutera*, 610 F.3d at 1112. Accordingly, Plaintiffs' arguments regarding Defendants' state of mind are irrelevant because the forward-looking statements at issue fall under Subsection A, not Subsection B.

Second, even if Defendants' state of mind was relevant—that is, even if the Court were to consider Plaintiffs' arguments under Subsection B —Plaintiffs would need to show that Defendants made forward-looking statements with "actual knowledge . . . that the statement[s] w[ere] false or misleading." Plaintiffs, in other words, would need to plead facts sufficient to raise a strong inference of scienter by Defendants. As the Court will discuss in the next section, the amended complaint fails to raise such an inference. Defendants' forward-looking statements thus fall under the purview of PSLRA's safe-harbor provisions, whether examined under Subsection A or under Subsection B.

In sum, Plaintiffs have identified four types of statements that Plaintiffs allege constitute material misrepresentations or omissions under § 10(b) and Rule 10b-5: (a) statements that relate

to the clinical history of Zalviso prior to submission of the NDA, (b) statements that trumpet Zalviso's alleged superiority to IV PCA, (c) statements that insufficiently disclose the risks and shortcomings of Zalviso, and (d) certain forward-looking statements. The Court finds that none of these statements constitute a material misrepresentation or omission sufficient to state a claim for liability under § 10(b) and Rule 10b-5.

2. Scienter

In order to survive a motion to dismiss, Plaintiffs' complaint must also give rise to a strong inference of scienter. With respect to the strong inference requirement, the Ninth Circuit has stated that "[a] strong inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Reese v. Malone*, 747 F.3d 557, 569 (9th Cir. 2014). With respect to the element of scienter itself, the "complaint must allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." *Zucco Partners, LLC v. Digimarc Corp.*, 562 F.3d 981, 991 (9th Cir. 2009) (internal quotation marks omitted). "[F]acts showing mere recklessness or a motive to commit fraud and [the] opportunity to do so" are insufficient. *Id.* "Rather, the plaintiff must plead a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Id.* (internal quotation marks omitted). In the Ninth Circuit, courts must determine first "whether any of the plaintiff's allegations, standing alone, is sufficient to create a strong inference of scienter." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1056 (9th Cir. 2014). If none is sufficient alone, the court must "then consider the allegations holistically to determine whether they create a strong inference of scienter taken together." *Id.*

The amended complaint alleges that Defendants knew about, but actively tried to hide, evidence of Zalviso's optical system errors, and that Defendants therefore made materially misleading statements about Zalviso's likelihood of approval either with intent or with deliberate

recklessness. Plaintiffs point to three categories of facts that allegedly give rise to a strong inference of scienter: (a) Defendants' decision to modify and improve upon Zalviso, (b) the importance of Zalviso to AcelRx's core operations, and (c) Defendants' financial motivations to commit fraud. Defendants dispute these contentions and argue that these facts in fact corroborate Defendants' central narrative: that Defendants submitted Zalviso's NDA in good faith, that Defendants planned to commercialize Zalviso in early 2015, and that Defendants were actively working to improve Zalviso's commercial potential. Following *In re NVIDIA*, the Court analyzes Plaintiffs' three categories of allegations in turn, before "consider[ing] the allegations holistically to determine whether they create a strong inference of scienter [when] taken together." *Id.*

a. Additional Device Modifications

Plaintiffs point first to a number of modifications that Defendants undertook on the Zalviso device prior to and during the class period. Plaintiffs single out AcelRx's patent filing records which, according to Plaintiffs, demonstrate that Defendants knew about the alleged optical system errors at issue. *See* Opp'n at 15–20.

Plaintiffs' narrative, however, is not "as compelling as any opposing inference of nonfraudulent intent." *Reese*, 747 F.3d at 569. As the Court has noted, Defendants contend that they submitted Zalviso's NDA in good faith and that they were continuously working to improve upon Zalviso. The amended complaint does not contradict this version of events. In fact, the amended complaint includes statements from Defendants that Defendants understood the optical system errors to be a "commercial issue," and not necessarily a regulatory issue. AC ¶ 83; *see also id.* ¶ 116 ("So firstly, what does the optical error rate have to get down to, it's not clear to be honest with you, we . . . thought it's being a commercial issue that we were addressing."). These facts corroborate Defendants' narrative rather than Plaintiffs' contention that Defendants acted with scienter. Under the circumstances, Defendants have thus presented an opposing inference of nonfraudulent intent that is at least as compelling (if not more compelling) than Plaintiffs' own inference.

On this particular point, the Court finds instructive the Ninth Circuit's decision in *In re*

NVIDIA. The plaintiffs in *NVIDIA* contended that NVIDIA was aware that some of NVIDIA's products were experiencing problems, and that executives at NVIDIA deliberately withheld this information from investors in order to buy time and to mislead shareholders. The Ninth Circuit rejected this theory. In reaching this result, the Ninth Circuit held that a defendant's decision to "delay[] disclosure while investigating the scope of [an] issue" does not give rise to a strong inference of scienter. 768 F.3d at 1065.

This same reasoning governs the instant case. Here, Defendants contend that Defendants were actively trying to determine the cause behind the optical system error rate, and it is plausible that Defendants might have delayed disclosure in order to investigate the scope of this issue. Plaintiffs have offered no factual basis to rebut this theory. Thus, following the reasoning in *In re NVIDIA* and the allegations in the amended complaint, the Court finds that Defendants' alleged modifications to Zalviso do not support a strong inference of scienter.

b. Zalviso's Importance to Core Operations

Next, Plaintiffs argue that the Court should find a strong inference of scienter because Zalviso "was, in a very real sense, AcelRx's core operation." Opp'n at 20. However, as Plaintiffs concede, the Ninth Circuit has typically "found inadequate complaints alleging that facts critical to a business's core operations or an important transaction generally are so apparent that their knowledge may be attributed to the company and its key officers." *Zucco Partners*, 552 F.3d at 1000 (internal quotation marks omitted). The Ninth Circuit recognizes two exceptions to this general rule. "The first exception permits general allegations about management's role in a corporate structure and the importance of the corporate information about which management made false or misleading statements to create a strong inference of scienter when these allegations are buttressed with detailed and specific allegations about management's exposure to factual information within the company." *Id.* (internal quotation marks omitted). "The second exception . . . permits an inference of scienter where the information misrepresented is readily apparent to the defendant corporation's senior management." *Id.* at 1001. "[R]eporting false information will only be indicative of scienter where the falsity is patently obvious." *Id.*

Defendants' actions do not fall under either of these exceptions. Both exceptions require management to have, at a minimum, made false or misleading statements. As the Court has held, however, Defendants did not make any such statements. Moreover, Plaintiffs have failed to show that whatever false information Defendants allegedly reported was "patently obvious." To be clear, knowing about the existence of certain optical system errors and knowing that one should report these errors to the public are two different things. Defendants might well have known about the optical system errors that afflicted Zalviso. Defendants might well have tried to address some of these errors prior to and during the class period. However, Defendants contend that Defendants did not know that the error rate would jeopardize regulatory approval for Zalviso, and Defendants contend that the FDA never did anything to dissuade Defendants of this belief. Plaintiffs have not challenged these contentions. It was therefore not "patently obvious" to Defendants that Zalviso's optical system errors would jeopardize Zalviso's chances for FDA approval.

In light of these circumstances, the Court rejects Plaintiffs' core operations theory. The Court finds that Plaintiffs have failed to sufficiently allege that Defendants made false or misleading statements or that Defendants acted with intent or with deliberate recklessness in making any such statements.

c. Financial Motives for Fraud

Finally, Plaintiffs point to Defendants' alleged financial motivations to commit fraud. Namely, Plaintiffs allege (i) that Defendants sought to increase their personal financial wealth, (ii) that Defendants sought to obtain a first mover advantage for Zalviso, and (iii) that Defendants sought to obtain financing and broker partnership opportunities during the class period. The Court will review these allegations in turn.

i. Increases to Personal Financial Wealth

First, Plaintiffs spend several paragraphs in the amended complaint describing AcelRx's executive compensation structure. *See, e.g.*, AC ¶¶ 140–46. Plaintiffs point to the fact that compensation for the individual Defendants was tied to certain goals, such as "completion of a partnership deal for Zalviso" and "obtaining positive top-line results" in Phase 2 and Phase 3

trials. *Id.* ¶ 141. "Thus, Defendants' misrepresentations and omissions to the market about Zalviso . . . made it possible for them . . . to increase their compensation." *Id.* ¶ 142.

This argument lacks merit. First, the Court fails to see how the existence of certain goals can, by themselves, lend support to a strong inference of scienter. If nothing else, these goals serve as practical targets that any company would set in order to encourage executives to work towards a larger common goal: to take a product to market. Second, and more importantly, the facts in this case simply do not corroborate Plaintiffs' narrative. During the class period, individual Defendants King, Palmer, and Welch actually increased their respective stock holdings in AcelRx.[4] King, Palmer, and Welch thus suffered significant financial losses as a result of their holdings in AcelRx—losses that dwarfed their actual compensation. *See* ECF No. 37 ¶ 13.

In the amended complaint, for instance, Plaintiffs allege that King was paid $2,631,565 in compensation in 2013, inclusive of salary, option awards, and other compensation. AC ¶ 143. During the class period, however, King lost approximately $4,609,377 in value as a result of King's holdings in AcelRx. ECF No. 37 ¶ 13. Plaintiffs allege that Palmer was paid $2,023,519 in compensation in 2013, inclusive of salary, option awards, and other compensation. AC ¶ 146. During the class period, however, Palmer lost approximately $4,732,773 in value as a result of Palmer's holdings in AcelRx. ECF No. 37 ¶ 13. Plaintiffs allege that Welch was paid $963,145 in compensation in 2013, inclusive of salary, option awards, and other compensation. AC ¶ 144. During the class period, however, Welch lost approximately $1,014,042 in value as a result of Welch's holdings in AcelRx. ECF No. 37 ¶ 13.

The Court fails to see how the individual Defendants were financially motivated to mislead investors about Zalviso. To emphasize: King, Palmer, and Welch increased their holdings in AcelRx during the class period and, as a result, suffered financial losses that dwarfed their actual compensation. There is no plausible reason—and, indeed, Plaintiffs have offered none—for the individual Defendants to have increased their personal investment in Zalviso if, in fact, the

[4] The remaining individual Defendant, Morris, was not employed by AcelRx during the class period and did not own shares of AcelRx during the class period. *See* ECF No. 37 ¶ 13 n.1.

individual Defendants knew that the FDA would likely withhold approval for Zalviso. *See In re Pixar Sec. Litig.*, 450 F. Supp. 2d 1096, 1107 (N.D. Cal. 2006) ("[T]he absence of insider trading by a defendant is highly relevant and undermines any inference of scienter.").

ii. First Mover Advantage

Next, Plaintiffs argue that Defendants sought to obtain a first mover advantage for Zalviso, so that the product would reach the market before the competition. Plaintiffs single out IONSYS, another "needle-free, patient-activated . . . analgesic system" developed by The Medicines Company. AC ¶ 131. According to Plaintiffs, Defendants rushed Zalviso through the approval process so that Zalviso would become the leading alternative to IV PCA rather than IONSYS.

Plaintiffs' argument is not well taken. Had Defendants actually known that the FDA would reject Zalviso, there would have been no point in rushing Zalviso through the regulatory approval process. The first mover advantage goes to the company that makes it to the market first, not to the company that gets rejected first. The alternative scenario is that Defendants honestly believed that Zalviso would receive FDA approval but—like all drugs submitted to the FDA—understood that such approval was not guaranteed. This alternative scenario, however, undermines a finding of scienter. Rather, this scenario lends support to Defendants' narrative that Defendants submitted Zalviso's NDA in good faith, that Defendants planned to launch Zalviso after FDA approval, and that Defendants were actively working to improve Zalviso's commercial viability.

To summarize, Defendants either believed Zalviso would be rejected or believed that Zalviso would be approved by the FDA. Under the former scenario, Defendants could not have been motivated by a first mover advantage. Under the latter scenario, Defendants' genuine belief in Zalviso's approval undermines an inference that Defendants made false or misleading public statements either with intent or with deliberate recklessness.

iii. Financing and Partnership Opportunities

Plaintiffs also point to certain financing and partnership opportunities of which Defendants allegedly sought to take advantage. *See* AC ¶ 137–38. Specifically, Plaintiffs allege that

Defendants were motivated to mislead the public in order to obtain financing from an investment firm, and that Defendants "were looking for potential companies to partner with in the United States." *Id.* The Court fails to see how these opportunities support an inference of scienter. All that Plaintiffs have managed to describe are common business practices that virtually all companies undertake. More importantly, Defendants' alleged actions are again entirely consistent with Defendants' own narrative: Defendants sought financing in order to help take a core product to market and Defendants sought partners in order to help distribute this product. The Court finds that these financing and partnership opportunities do not give rise to a strong inference of scienter.

d. Holistic Evaluation

As a final step, the Court must examine whether Plaintiffs' allegations, taken together, sufficiently support a strong inference of scienter. Considered holistically, these allegations do not create an inference of scienter that is "as compelling as any opposing inference of nonfraudulent intent." *Reese*, 747 F.3d at 569. According to Plaintiffs, Defendants acted with scienter because (1) Defendants actively made changes to the design of Zalviso, (2) Zalviso formed AcelRx's core operation, and (3) Defendants had financial incentives to commit fraud. However, an opposing inference of nonfraudulent intent is equally if not more compelling. Defendants could have submitted Zalviso for FDA approval in good faith. Defendants could have been trying to make changes to Zalviso in order to make the product more commercially viable. The individual Defendants could have acquired additional shares of AcelRx during the class period because the individual Defendants sincerely believed that Zalviso would receive FDA approval. Because Plaintiffs have failed to contradict any of these plausible inferences that do not implicate fraud, the Court finds that Plaintiffs have failed to allege facts sufficient to support a strong inference of scienter.

In conclusion, Plaintiffs have failed to state a claim upon which relief may be granted. The amended complaint fails to plead facts sufficient to show that Defendants committed a material misrepresentation or omission or that Defendants acted with scienter. Defendants' motion to dismiss is therefore GRANTED.

B. Violation of § 20(a) of the Exchange Act

Plaintiffs also allege that the individual Defendants—Palmer, King, Welch, and Morris—should be held liable as controlling persons under § 20(a) of the Exchange Act. Under § 20(a), "a defendant employee of a corporation who has violated the securities laws will be jointly and severally liable to the plaintiff, as long as the plaintiff demonstrates a primary violation of federal securities law and that the defendant exercised actual power or control over the primary violator." *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 711 (9th Cir. 2012) (internal quotation marks omitted). The Court finds dismissal of Plaintiffs' § 20(a) claim appropriate because Plaintiffs have failed to state an underlying violation of federal securities law. Accordingly, the Court GRANTS Defendants' motion to dismiss Plaintiffs' § 20(a) claim.

C. Leave to Amend

Plaintiffs shall have leave to amend because the Court finds that amendment would not necessarily be futile, as Plaintiffs may be able to allege sufficient facts to show, for instance, that Defendants knew that Zalviso would be denied approval or that Defendants did in fact act with intent or with deliberate recklessness. *See Lopez*, 203 F.3d at 1127 (holding that "a district court should grant leave to amend . . . unless it determines that the pleading could not possibly be cured by the allegation of other facts.") (internal quotation marks omitted). Should Plaintiffs elect to file an amended complaint, Plaintiffs must specify what statements made by Defendants were misleading, how these statements were misleading, and why Defendants' alleged omissions, if disclosed, would have made these statements not misleading. In addition, Plaintiffs must specify what actions by Defendants give rise to a strong inference of scienter, and not an opposing inference that Defendants acted in good faith.

V. CONCLUSION

For the reasons stated above, Defendants' motion to dismiss is GRANTED with leave to amend. Should Plaintiffs elect to file an amended complaint curing the deficiencies identified herein, Plaintiffs shall do so within 30 days of the date of this Order. Failure to meet the 30 day deadline to file an amended complaint or failure to cure the deficiencies identified in this Order

will result in a dismissal with prejudice. Plaintiffs may not add new causes of actions or parties without leave of the Court or stipulation of the parties pursuant to Federal Rule of Civil Procedure 15.

IT IS SO ORDERED.

Dated: November 25, 2015

LUCY H. KOH
United States District Judge